California HIV/AIDS Surveillance

Standard Operating Procedures

External

Quick Start-Up Guide

for the Laboratory Data Entry Tool (LDET)

Version 4.04

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LDET Standard Operating Procedures

REVISION HISTORY

Version #	Revision Date	Summary of Changes	Revised By
1.0	08/25/2011	Initial draft	Victor Borromeo
1.5	09/06/2011	Reformatted	Steven Starr
2.0	10/19/2011	Edited	Gary Horpedahl
2.5	2/21/2012	Note: CD4 transitioning from HIV to AIDs	Gary Horpedahl
3.0	02/20/2013	Edited	Julia Zuo
4.04	04/10/2015	Updated	Brian Bannister & Scott Masten

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1   What Is LDET?

The Laboratory Data Entry Tool, or LDET, is a secure and efficient system for Local Health Jurisdictions (LHJs) to send HIV-infection-related test results received from health care providers and laboratories to the California Department of Public Health, Center for Infectious Diseases, Office of AIDS (OA) HIV Surveillance Section. LDET is a Microsoft Access database created by OA into which LHJ staff enter HIV-infection-related test results they receive from laboratories and then upload the resulting electronic files to OA to be uploaded directly into the Enhanced HIV/AIDS Reporting System (eHARS).

Entering laboratory results through LDET ensures that format and value requirements for laboratory data imposed byeHARS are correctly met, which prevents rejection of the laboratory records during the eHARS import process. To make this possible, the following data controls were designed into the LDET system:

- The application's data entry screens require the user to enter data into required fields.

- Field values require that data be entered in a specific way to make it acceptable to the eHARS import template and are selectable only from a drop-down list, ruling out unexpected data.

- Default values are automatically entered into some of the required fields when adding a new laboratory record, assuring that they are not left blank.

2   System Requirements and Installation

LDET is available to download from the OA Secure File Transfer (SFT) site, not from the OA website. Please contact your OA Surveillance Coordinator to get specific details regarding where to download LDET, and obtain an LDET Username and Password for your LHJ.

To protect confidentiality of patient data, LDET should only be installed on a password-protected system with an encrypted hard drive that is either connected to your LHJ's secure network/server or is a standalone PC.

2.1   System Requirements
- Access version 2007 or later full installation or Access Runtime installation
- Internet connection (to download the installation files and upload laboratory data to OA)

2.2   Technical Support and Contact Information
For LDET technical support questions, please email: LDETTECH@cdph.ca.gov

Contact information: http://www.cdph.ca.gov/programs/aids/Documents/SSContactList.pdf

2.3   LDET Installation
1. Click here: https://sft.ca.gov/ (this will take you to your specific LHJ's folder)

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> Username: (this will be assigned to you by OA)
> Password: (this will be assigned to you by OA)

2. Download (save) the file to any destination.

3. Double-click the downloaded file (ldetX_LHJspecific.exe), where "X" represents the current version of LDET. Browse to the location, usually on a secure network, where you want to store LDET at your LHJ. When you've selected the folder, click "UNZIP".

4. Navigate to the folder you browsed to in the step above.

5. Double click the file named "ldetX.accdr" (it may also appear without the extension, i.e., "ldetX") to open it, again where the "X" represents the current version of LDET.

6. You will be prompted to browse to the location of the back end. Simply click to browse, and navigate to the location where you've stored all the LDET files. You will see the "ldetX_be" file; double click that to select it.

7. You'll be notified that the front and back ends have been connected.

8. The password for your site will be assigned to you by OA. There is no username; all LDET users at your site will log in with the assigned password.

9. If you are asked whether to "import the CLIA file," choose "Yes."

10. Done; you'll be at the LDET Main Page.

2.4 Desktop Shortcut
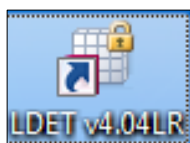
After the installation process, a shortcut to the application can be installed to your desktop. Right click on the LDETX.accr file, scroll down to "Send to" and select "Desktop (create shortcut)." The shortcut shown to the left will appear on your desktop. You can rename this shortcut if you'd like. Double-clicking on this desktop shortcut opens the LDET Main Page.

2.5 Overview of How LDET Works

LDET stores information about cases (persons) who can have one or more laboratory results. Any time you want to enter a laboratory result into LDET, you must first determine if the case already exists in LDET (searching for an existing case), or whether the case details will need to be newly entered because this is the first time a laboratory result has been entered for the case (creating a new case).

Note that unlike previous versions of the LDET, STATENOs are now unique and cannot be duplicated across cases. That is, LDET no longer allows you to enter a STATENO that has been entered for a previous case, because laboratory results are now grouped by case (STATENO).

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LDET will allow you to: **edit** case details or laboratory results that were entered previously; **add** new laboratory results to an <u>existing</u> case; **delete** a case or laboratory result completely; or **add** a <u>new</u> case so that you can then add laboratory results for that case. The first step to perform any of these actions is to search for the case in LDET, which is explained in the next few sections.

2.6   The LDET Main Page

The LDET Main Page is the first screen you'll see when you enter your password and log into LDET. Any time you want to view, enter, edit, or delete case details or laboratory records, you will start from this page. For instructions about how to perform these functions, see the appropriate sections of this document.

If you have never entered data into LDET, you will not see any data listed on the Main Page.

LDET Main Page Displaying No Previously Entered Data

If you have upgraded to a newer version of LDET, the LDET Main Page should display all the cases that you previously entered.

LDET Main Page Displaying Previously Entered Cases

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3   Searching for an Existing Case

If a case already exists in LDET, you do not need to enter all the case details each time you enter another laboratory result for the case, because LDET will populate all the case details for you. To find the existing case, you need to perform a search of LDET on the LDET Main Page using the STATENO, Last Name, or Date of Birth of the case.

3.1   Searching for a Case using a Complete or Partial STATENO
To search for a case in LDET using the person's STATENO, enter the STATENO in the "STATENO" box on the LDET Main Page and click the "Search" button. For example, you might enter the STATENO "2345566766" because it was written on a laboratory report.

Search for Complete STATENO to Determine if the Case Already Exists in LDET

Any case matching the STATENO will be displayed in the lower portion of the page.

Existing Case Matching the Complete STATENO is Found and Displayed

Alternatively, you can search for a case using a partial STATENO. For example, instead of entering all digits of "111222333", you can enter only "111" and all cases with a STATENO beginning with "111" will be displayed.

Existing Cases with STATENOs that Match the Partial STATENO

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3.2 Searching for a Case using Last Name

To search for a case in LDET using the person's last name, enter the last name of the case in the "Last Name" box on the LDET Main Page and click the "Search" button. Alternatively, you can search for a case using a partial last name. For example, instead of entering "Hutt", you can enter only the letter "H" (not case-sensitive and no quotes) and all cases with last names beginning with "H" will be displayed.

Searching for a Case Using a Partial Last Name

3.3 Searching for a Case using Date of Birth

To search for a case in LDET using the person's date of birth, enter the date of birth of the case in the "Date of Birth" box on the LDET Main Page and click the "Search" button. Alternatively, you can search for a case using a partial date of birth. For example, instead of entering "9/20/1978", you can enter "9/20" and all cases with a date of birth beginning with "9/20" will be displayed.

Searching for a Case Using a Partial Date of Birth

3.4 Clearing Search Results

You must clear any previous search results by clicking the "Clear" button before doing a new search. This will reset the LDET Main Page listing and return it to original status, which is a list of all the unique cases in LDET.

Click "Clear" to Clear the Search Results and Show All Cases Again

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3.5 What to do once an Existing Case is Identified

Once you find the existing case using the search functions, click the number in the "RecNo" column beside the case to display the Edit Laboratory Info screen to see case details.

Click on the Number in the "RecNo" Column for an Existing Case to See Case Details

The Edit Lab Info screen should now display for the case you chose. This screen shows the case details for the person on the top of the screen, and a list of the laboratory results associated with this case at the bottom of the screen. Click the "Add Lab Tests" button to add a new laboratory result for this case, or click "Exit Edit View" to return to the LDET Main Page.

Edit Lab Info Screen Showing Existing Case Details and Associated Laboratory Results

See the Reporting Laboratory Results section for instructions about how to enter a laboratory result for the existing case you identified.

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4 Creating a New Case

If you can't find a case using a complete or partial STATENO, Last Name, or Date of Birth, the case is a new case for which a laboratory result has never been entered into your stand-alone LDET. Before assigning a STATENO to the case, search your Data Use Agreement (DUA) dataset, if your jurisdiction has one. Some cases may be in the DUA dataset, but do not yet have laboratory results entered into LDET. Information about obtaining a DUA dataset for your LHJ can be found at: http://www.cdph.ca.gov/programs/aids/pages/survprocedures.aspx. You should also conduct a case check with OA before assigning a STATENO to the case to determine if it has been assigned a STATENO by another LHJ. Information about case checks can also be found at: http://www.cdph.ca.gov/programs/aids/pages/survprocedures.aspx. If you can't find the case through any of these means, then you must assign a STATENO and create a new case in LDET before you can enter laboratory results for this case. To do this, click the "Add Lab Info and Lab Tests" button on the LDET Main Page.

Click "Add Lab Info and Lab Tests" to Create a New Case

The Add Lab Info screen is displayed. This screen is used to create a new case from whom you would like to enter laboratory results, or to edit details for an existing case.

Blank Add Lab Info Screen Used to Create a New Case

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To create a new case so that you can then enter laboratory results for the case, follow the instructions in the following subsections to create a case by entering the information on the Add Lab Info screen.

4.1 Adding the STATENO for a New Case

The first piece of information required to create a new case on the Add Lab Info screen is the STATENO for the case. Enter the STATENO in the "STATENO" box and press the tab or enter key. A box will appear asking you to re-enter the STATENO and click "OK" to verify that you typed it correctly. Next you need to add other information for the new case.

Entering and Verifying the STATENO to Create a New Case

4.2 Entering Other Information for a New Case

Fields with yellow labels on the Add Lab Info screen must be completed to create a case. Besides STATENO, the minimum required information to create the new case is:

- Last Name
- First Name
- Date of Birth
- Sex at Birth

Fields with blue labels on the Add Lab Info screen are not required, but it is recommended that you also complete these fields to improve the correct importing of laboratory documents into eHARS. Optional information that can be entered for a case is:

- Middle Name
- Suffix
- Medical Record Number
- Prison Number

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When entering Last Name, First Name, or Middle Name, you do not have to do proper casing. For example, if you enter "**skywalker**" in lower case for a Last Name, the system converts it to "**Skywalker**"; entering "**luke**" for the First Name becomes "**Luke**"; and entering "**a**" for the Middle Name converts to "**A**".

Enter Suffixes such as JR, SR, II or III in the "Suffix" field; please do not enter suffixes in the "Last Name" field.

Pressing the **Enter** or **Tab** key takes you to the next field.

Additional information about these LDET variables can be found in Appendix A.

4.3 What to do once an New Case is Created

The screenshot below shows complete information entered on the Lab Info Screen to create a new case for which laboratory records can now be entered. Once you've similarly entered all the information to create your new case, click the "Add Lab Tests" button to add laboratory results for this case.

Click on the "Add Lab Tests" Button to Add Laboratory Results for a Newly Created Case

<div style="color:red; font-weight:bold;">
See the Reporting Laboratory Results section for instructions about how to enter a laboratory result for the new case you created.
</div>

5   Reporting Laboratory Results

Prior to entering laboratory results, you must have either: (a) searched LDET and found the case if it already existed in LDET, or (b) created a new case using the procedures in the prior section. Click the "Add Lab Tests" button to add a new laboratory result for this case

Edit Lab Info Screen Showing Existing Case Details and Associated Laboratory Results

When you click the "Add Lab Tests" button for the case you found/created, the Add Lab Test screen is displayed. Instructions for completing the fields on this screen to enter a laboratory result for a case are presented in the following subsections.

Blank Add Lab Test Screen Used to Add Laboratory Results for a Case

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5.1 Entering Information for a Laboratory Result

Fields with yellow labels on the Add Lab Test screen must be completed to add a laboratory result for a case. Note that the fields that are required change depending on the type of laboratory result being reported and the date the case was first reported in LDET as being HIV positive. The information required to enter a laboratory result for a case is:

- Specimen Collection Date (the date the specimen for the test was drawn from the case)
- Lab CLIA Number (the Clinical Laboratory Improvement Amendments number)
- Accession Number (only during first 90 days of HIV positive status)
- Lab Test Name (see Appendix B for more information)
- Test Result/Interpretation (see Appendix B for more information)

Fields with blue labels on the Add Lab Test screen are not required, but it is highly recommended that you also complete these fields to improve the correct importing of laboratory documents into eHARS. The optional information that can be reported for a laboratory result is:

- Date Received from Lab (the date the test result was received by your LHJ)
- Result Date (the date the test was conducted by the laboratory)
- Manufacturer (manufacturer of the test upon which the laboratory result is based)
- Rapid Test? (whether or not the laboratory result was based on a rapid test)
- Accession Number (after the first 90 days of HIV positive status)

Pressing the **Enter** or **Tab** key takes you to the next field.

Additional information about these LDET variables can be found in Appendix A.

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5.2 Entering Specimen Collection Date for a Laboratory Result

The first field that must be completed on the Add Lab Test screen to enter a laboratory result is the "Specimen Collection Date." This should be the date that the specimen upon which the result was based was drawn from the case. Please be as accurate as possible with this field.

Enter Specimen Collection Date for a Laboratory Result

Note that once you click tab or enter to go to the next field, LDET calculates the days between the specimen collection date and the date the laboratory result was entered into LDET. If this difference is colored red, there is a big time difference between the specimen collection date and the LDET entry date. In such cases, check the specimen collection date for accuracy to ensure that it was not incorrectly entered. The date in the example below is colored pink, indicating that the difference between the dates was less than 1 year.

LDET Calculation of the Difference between the Specimen Collection and LDET Entry Dates

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5.3   Entering the CLIA Number for a Laboratory Result

The next field that must be reported to enter a laboratory result on the Add Lab Test screen is the laboratory CLIA number. All laboratories certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Act have a number that uniquely identifies the laboratory. These CLIA numbers must be reported to LHJs for all HIV-infection-related tests per California Code of Regulations (CCR), Title 17, Section 2643.10(a). CLIA numbers are also needed so OA staff can request that the laboratory holding the specimen send it for further testing as part of the HIV Incidence Surveillance Program. If you do not know the CLIA number of a laboratory, you can look it up using the name, or a partial name, at: http://wwwn.cdc.gov/clia/Resources/LabSearch.aspx. Click the drop-down arrow for the "Lab CLIA No" box and select the laboratory, if it is already on the Lab Shortlist.

Click the Drop-Down Arrow on the "Lab CLIA No" Box to Select a Laboratory on the Lab Shortlist

5.3.1   Adding a Laboratory to the "Lab CLIA No" Drop-Down List (aka Shortlist)

If the laboratory is not shown in the drop-down list for the "Lab CLIA No" box, add it to this drop-down list by clicking the "Lab Shortlist Setup" button.

Click "Lab Shortlist Setup" if the Laboratory is Not Listed for a Laboratory Result

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This opens the Lab Shortlist Setup screen. You can search for a laboratory by partial CLIA, laboratory name, street address, city, or any combination of these as long as you separate your input by commas (e.g., "Quest, West Hills"). Here CLIA "05D0642827" for the West Hills location of Quest Diagnostics has been typed into the "Search Labs" box, and the "Search" button was clicked. Note that one laboratory was found that matches this CLIA.

Searching for a Laboratory to Add to the Lab Shortlist

The laboratory that matched CLIA "05D0642827" for the West Hills location of Quest Diagnostics can be seen by clicking the drop-down box for the CLIA/Lab Name field. If more than one laboratory met the search criteria, all these matching laboratories would be shown in this drop-down box.

Click the Drop-Down to See the Laboratories that Matched the Search Criteria

Note that there are many laboratories with the same, or similar, names, but different locations. Before selecting a laboratory to add, please ensure that the address matches the address for

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the laboratory associated with the test result being entered. If you need a laboratory added to the list of available labs, email LDETTECH@cdph.ca.gov and request that it be added.

Choose the correct laboratory and click the "Add this Lab" button. Click "Close Form" to return to the Add Lab Test screen.

Select and the Correct Laboratory and Click "Add this lab" to Add it to the Lab Shortlist

The newly added laboratory is now on the Lab Shortlist on the Add Lab Test screen and can be selected easily from the "Lab CLIA No" drop-down list now and in the future.

The Newly Added Laboratory is Now Shown on "Lab CLIA No" Drop-Down List

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5.4   Entering the Specimen Accession Number for a Laboratory Result

The next field that often must be reported to enter a laboratory result on the Add Lab Test screen is the laboratory-assigned specimen accession number. Accession numbers are tracking or inventory numbers found on laboratory reports and specimen vials that are used to track specimen and link them to patients. Accession numbers are required for all laboratory results with a specimen collection date that is within 90 days of the date of the first HIV positive laboratory result reported in LDET for the case. Accession numbers are needed so OA staff can request that the laboratory holding the specimen send it for further testing as part of the HIV Incidence Surveillance Program. While accession numbers are not required once the specimen collection date is past this 90-day window, including them allows OA to better identify duplicate laboratory results in eHARS, so LHJs are encouraged to always enter accession numbers.

Completed Specimen Accession Number for a Laboratory Result

Extra caution should be observed when it comes to recording specimen accession numbers, because the numbers may not be obvious in the laboratory reports, what they are called on laboratory reports varies, and their structure and format are different across laboratories. While the content and formatting of accession numbers varies across laboratories, they are usually a string of numbers or combination of letters and numbers. If you click the question mark next to the "Accession No" field on the Add Lab Test screen, the formatting for several common laboratory accession numbers is shown. For guidance identifying the accession numbers on laboratory reports for other common laboratories, see the Guide to Accession Number Identification from Common Laboratories available on the OA website at:
http://www.cdph.ca.gov/programs/aids/Documents/GuideToAccessionNumberIdentificationFromCommonLaboratories2.pdf

If you are unsure about how to identify the correct accession number to report, you may contact the laboratory directly or the HIV Surveillance Laboratory Coordinator at OA, Jessica Brown, at (916) 445-9231 or Jessica.Brown@cdph.ca.gov.

5.5 Entering the Test Name and Result/Interpretation for a Laboratory Result

The next fields that must be reported to enter a laboratory result on the Add Lab Test screen are the laboratory test name and the actual result/interpretation of the test. Click the "Lab Test Name" drop-down arrow to reveal the test types available in LDET, which are grouped into major categories of test types. Note that different test result/interpretation fields will appear based on the laboratory test name that is selected.

Lab Test Names Available in LDET

If you are unsure of which laboratory test name to select for laboratory results you've received, contact your OA Surveillance Coordinator for assistance.

Some tests have been "retired" that were available in earlier versions of LDET. Although these retired tests are still frequently being used, they should now be entered as the general type of test. For example, "HIV-1 RNA BDNA" and "HIV-1 RNA RT-PCR" are no longer listed in the drop-down list, because these quantitative viral load tests should now be entered as "HIV-1 RNA/DNA NAAT (QUAN)." Similarly, the retired "HIV-1 RNA PCR (QUAL)" and "HIV-1 PROVIRAL DNA (QUAL)" should now be entered as "HIV-1 RNA/DNA NAAT (QUAL)."

Whether a test was rapid or not can now optionally be reported for all applicable tests.

Additional information about the test types in LDET can be found in Appendix B.

The following subsections demonstrate how to enter results for one example of each of the major categories of tests.

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5.5.1 Entering Results for HIV Antibody Non-Type Differentiating Tests

To enter results for a non-type differentiating HIV antibody test (e.g., 4th generation HIV-1/2 antigen/antibody combination immunoassay [EIA]), select the correct option from the "Lab Test Name" drop-down. Then select the actual test result from the "Lab Result" drop-down box.

Result Screen for Non-Type Differentiating HIV Antibody Tests

5.5.2 Entering Results for HIV Antibody Type Differentiating Tests

To enter results for a type differentiating HIV antibody test (e.g., Multispot), select the correct option from the "Lab Test Name" drop-down. Then select the actual test result from the "Differentiating Result" drop-down box.

Result Screen for Type Differentiating HIV Antibody Tests

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5.5.3   Entering Results for Qualitative HIV Detection Tests

To enter results for a qualitative HIV detection test (e.g., a <u>qualitative</u> HIV-1 RNA PCR or HIV-1 PROVIRAL DNA), select the correct option from the "Lab Test Name" drop-down. Then select the actual test result from the "Lab Result" drop-down box.

Result Screen for Qualitative HIV Detection Tests

5.5.4   Entering Results for Quantitative HIV Detection Tests

To enter results for a quantitative HIV detection test (e.g., a <u>quantitative</u> HIV-1 RNA BDNA or HIV-1 RNA RT-PCR) <u>with a detectable viral load</u>, select the correct option from the "Lab Test Name" drop-down. Then select the actual interpretation of the test result from the "Lab Interpretation" drop-down box. In the boxes under "Lab Result" enter the reported copies per milliliter (Copies/ML), along with the logarithm of the viral load (LOG), if it is known.

Result Screen for Quantitative HIV Detection Tests with Detectable Viral Load

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To enter results for a quantitative HIV detection test <u>with an undetectable viral load</u>, select the correct option from the "Lab Test Name" drop-down. Then click the "Undetectable Viral Load" box. The "Lab Interpretation" and "Copies/ML" will be automatically filled in by LDET.

Result Screen for Quantitative HIV Detection Tests with Undetectable Viral Load

5.5.5 Entering Results for Immunologic Tests

To enter results for an immunologic test (e.g., CD4+ T-cell count or percentage), select the "CD4 COUNT" option from the "Lab Test Name" drop-down. Then enter the actual CD4 count in the "CD4 Count" box, followed by with the CD4 percent in the "CD4 Percent" box, if it is known.

Result Screen for Immunologic Tests

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> **If the CD4+ count is <200, or if not present, the CD4+ T-cell percent is <14 percent:**
> If this laboratory is the first test result meeting either above criterion for a known HIV case, then the case has transitioned to AIDS. For such cases you must complete an Adult Case Report Form (ACRF) and send it to OA for entry into eHARS. The ACRF should include: the residence at AIDS diagnosis, the medical facility that made the AIDS diagnosis or ordered the CD4 test, the actual laboratory results, the specimen collection date, and any other known case information. **The test result SHOULD ALSO be entered into LDET.**

5.6   When you are Done Entering a Laboratory Result

When you are finished entering a laboratory result, click the "Validate/Exit" button at the top of the Add Lab Test screen to return to the Edit/Add Lab Info screen. If you have missed any required fields, one or more boxes will appear warning you about the missing information.

Add Lab Test

Add Lab Test for Stateno   77899   **Validate/Exit**

Click "Validate/Edit" when Done Entering a Laboratory Result

5.7   When you are Done Entering All Laboratory Test Results for a Case

You may enter additional test results for a case by clicking the "Add Lab Tests" button on the Edit/Add Lab Info screen again. When you are finished entering all laboratory results for a case, click the "Exit Edit View" or "Exit Add View" button to return to the LDET Main Page.

Edit Lab Info

Edit Lab Info for STATENO 77899   **Exit Edit View**

Lab Info

Labels in yellow are required information when importing a lab document into eHARS

Record Number	34
Parent ID	
Rollup Number	
Document Type	004
STATENO	77899
Date Lab Case Entered	2/23/2015
Site Code	CA31

Labels in blue are highly recommended information when importing a lab document into eHARS

Last Name	Solo	Suffix		Medical Record No	999 Millennium Falcon
First Name	Han			Prison No	Carbonite1980
Middle Name	Corellia				
Date of Birth	5/25/1977	Age 37 on 2/23/2015			
Sex at Birth	M	Male			

Edit or Add Lab Tests for STATENO 77899   **Add Lab Tests**

Unsent labs missing collection date, test name or result will be marked in RED in the RecNo column. Please complete these or delete them. [?]

	RecNo	STATENO	Date Entered	Receive Date	Collection Date	Lab Test Name	Lab Result	Lab Units	Interpretation
	182	77899	2/23/2015		1/2/2015	HIV-1 EIA	POS		
	181	77899	2/23/2015		1/2/2015	NON-TYPE DIFF. HIV 1/2 A(	POS		
*	(New)	77899							

Click "Exit Edit View" or "Exit Add View" when Done Entering All Laboratory Results for a Case

6 Exiting LDET

When you are finished entering all laboratory results for cases into LDET, click the "Quit" button on the LDET Main Page and then click "Yes" to confirm that you want to exit LDET. All changes that you made are automatically saved when you exit.

Click "Quit" and Confirm "Yes" to Exit LDET

7 Editing or Adding Information for an Existing Laboratory Result

Sometimes you need to edit or update the information for an existing laboratory result. To do this, first perform a search to find the case on the LDET Main Page. When you find the case, click the "RecNo" number beside the case to display the Edit Laboratory Info screen. For example, to correct a CD4 count of "437" that was incorrectly entered as "4370" for Yoda, the "37" in the "RecNo" column next to Yoda's name would be clicked.

Click on the Number in the "RecNo" Column to Select the Case with the Laboratory Result to Edit

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The Edit Lab Info screen should now display for the case you chose. This screen shows the case details of the case on the top of the screen, and a list of the laboratory results associated with this case at the bottom of the screen. Click the "RecNo" of the laboratory result you want to edit, which will open the Edit Lab Test screen for that laboratory result.

Click on the Number in the "RecNo" Column to Select the Laboratory Result to Edit

The Edit Lab Test screen should now display for the laboratory result you chose. This screen shows the details of the test result, which you can now edit or update.

Edit Lab Test Screen Displaying Incorrect Laboratory Result

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When you are done updating the laboratory result information, click the "Validate/Exit" button to return to the Edit Lab Info screen. Note Yoda's CD4 count has been corrected.

Corrected Laboratory Result on the Edit Lab Test Screen

The corrected result, in this case the CD4 count for Yoda, is now displayed on the Edit Lab Info screen. Click "Exit Edit View" to return to the LDET Main Page.

Edit Lab Info Screen Displaying Corrected Laboratory Result

Note: If the test result you corrected was previously uploaded to OA in uncorrected form, the changes will not be known to OA unless you also submit a paper update of the result to OA.

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8 Editing or Adding Information for an Existing Case

Sometimes you obtain additional details about a case that you want to add (e.g., Medical Record Number) or you need to correct details for the case (e.g., you incorrectly assigned STATENO "56689" to a case that should actually be STATENO "345699"). To do this, first perform a search to find the case on the LDET Main Page. When you find the case, click the "RecNo" number beside the case to display the Edit Lab Info screen. For example, to change the STATENO for Jabba the Hutt to "345699," click the "35"in the "RecNo" column.

Click the "RecNo" on the LDET Main Page to Edit Details for the Entire Case

The Edit Lab Info screen should now display for the case you chose. This screen shows the case details of the case on the top of the screen, and a list of the laboratory results associated with this case at the bottom of the screen. You can edit the case detail fields that are not locked: STATENO, Last Name, First Name, Middle Name, Date of Birth, Sex at Birth, Medical Record Number, and Prison Number. When you are done, click the "Exit Edit View" button to return to the LDET Main Page. Note that Jabba the Hutt's STATENO has been corrected.

Edit Laboratory Info Screen Showing Case Details and Listing of Associated Laboratory Results

Note that Jabba the Hutt's STATENO has been changed to "345699" on the LDET Main Page for in this example.

LDET Main Page Showing Updated STATENO for the Edited Case

> **Warning: If your edit involves changing the STATENO, LDET makes a cascading change to <u>all</u> STATENOs for laboratory results associated with the case. For example, if you change the STATENO "56689" to "345699", the STATENO is automatically changed to the new STATENO for all laboratory results for that case.**
>
> **Note: If the laboratory results you corrected were previously uploaded to OA in uncorrected form, the changes will not be known to OA unless you also submit paper updates of the laboratory results to OA.**

9   Deleting an Entire Existing Laboratory Result

Sometimes you want to delete an entire laboratory result (e.g., delete a laboratory result mistakenly put on the wrong case). To do this, first perform a search to find the case on the LDET Main Page. When you find the case, click the "RecNo" number beside the case to display the Edit Laboratory Info screen. For example, to delete a CD4 Percent result for Lando Calrissian, click the "38" in the "RecNo" column next to his name.

Click on the Number in the "RecNo" Column to Select the Matching Case

LDET Standard Operating Procedures

The Edit Lab Info screen should now display for the case you chose. This screen shows the case details of the case on the top of the screen, and a list of the laboratory results associated with this case at the bottom of the screen. Click the GRAY AREA next to the "RecNo" of the laboratory result you want to delete, which will highlight the entire test result row.

Click the Gray Area Next to the Laboratory Result You Want to Delete and Press the "Delete" Key

Press the "Delete" key on your keyboard and a warning message will pop up confirming that you want to delete the laboratory result entirely. Click "Yes" to confirm the deletion.

Click "Yes" to Confirm the Deletion of the Laboratory Result

LDET Standard Operating Procedures

The undesired test result is no longer showing in the Edit Lab Info page because it has been deleted. Click "Exit Edit View" to return to the LDET Main Page.

Click "Exit Edit View" to Return to the LDET Main Page

> **Note: If the laboratory result you deleted was previously uploaded to OA, the deletion will not be known to OA unless you also submit a paper update to OA.**

10 Deleting an Entire Existing Case

Sometimes you want to delete an entire case and all associated laboratory results. To do this, first perform a search to find the case on the LDET Main Page. When you find the case, click the "RecNo" number beside the case to display the Edit Lab Info screen. For example, to delete Lando Calrissian entirely, click the "Click to delete" in the "Delete Case" column.

Click the "Click to delete" on the LDET Main Page to Delete an Entire Case

LDET Standard Operating Procedures

A warning appears confirming you want to delete the entire case and all associated laboratory results. Click "Yes" to confirm the deletion of the case.

Click "Yes" when the Warning Appears to Delete the Entire Case

Another warning appears requiring you to type the word "delete" and click "OK" to confirm again that you want to delete the entire case and all associated laboratory results. Type "delete" and click "OK" to confirm the deletion of the case.

Type "delete" and Click "OK" to Finally Delete the Case

The case and all associated laboratory results are now deleted from LDET and the case no longer shows on the LDET Main Page. Click "OK" to finish.

LDET Main Page with the Case Deleted; Click "OK" to Finish

> **Note: If laboratory results for the case you deleted were previously uploaded to OA, the deletions will not be known to OA unless you also submit a paper update to OA.**

11 Exporting Laboratory Results from LDET to Send to OA

Laboratory results you enter into LDET are not automatically exported to OA. At least once a month you must export the completed laboratory results from LDET and upload them to the OA Secure File Transfer (SFT) server. The "Export Data to Send to OA" button on the LDET Main Page tells you if, and how many, laboratory result records are ready to be exported and sent to OA.

LDET Main Page Showing Laboratory Results Ready to be Exported and Sent to OA

LDET Standard Operating Procedures

To export the laboratory results to a file that can then be uploaded to the SFT, click the "Export Data to Send to OA" button on the LDET Main Page. A warning asking you to confirm the export will appear. Click "Yes" to begin the export. Note that when you export laboratory results, copies of the results also stay in LDET (i.e., they don't disappear from LDET).

Click the "Export Data to Send to OA" Button on the LDET Main Page to Export Laboratory Results

Another warning appears requiring you to type the word "export" and click "OK" to confirm again that you want to export the laboratory results. Type "export" and click "OK" to confirm the export of the laboratory results to a file that can then be uploaded to OA.

Type "export" and Click "OK" to Finally Export the Laboratory Results

LDET Standard Operating Procedures

A box appears telling you where the file containing the exported laboratory results has been created by LDET. In the case below the file was created in "C:\ldet3\transfer". Write the location down where your LDET export file was created before proceeding. Click "OK" to proceed.

**Box Showing the Location where the Laboratory Results were Exported; Write it Down and Click "OK"**

After you export the laboratory results, the "Export Data and Send to OA" button will show "0 sendable" to indicate that all the available records were exported to a file that can now be upload to the OA SFT.

The "Export Data to Send to OA" Button on the LDET Main Page Confirms the Results were Exported

LDET Standard Operating Procedures

The location of the file containing the exported laboratory results that can now be transferred to OA's SFT is shown below. The location may be different on your system. Note that you have not yet actually sent anything to OA. The file you just created still needs to be uploaded to the OA SFT. Instructions regarding how to use the Secure File Transfer Protocol (SFTP) network to upload the exported file containing the laboratory results to OA's SFT are available at: http://www.cdph.ca.gov/programs/aids/pages/survprocedures.aspx
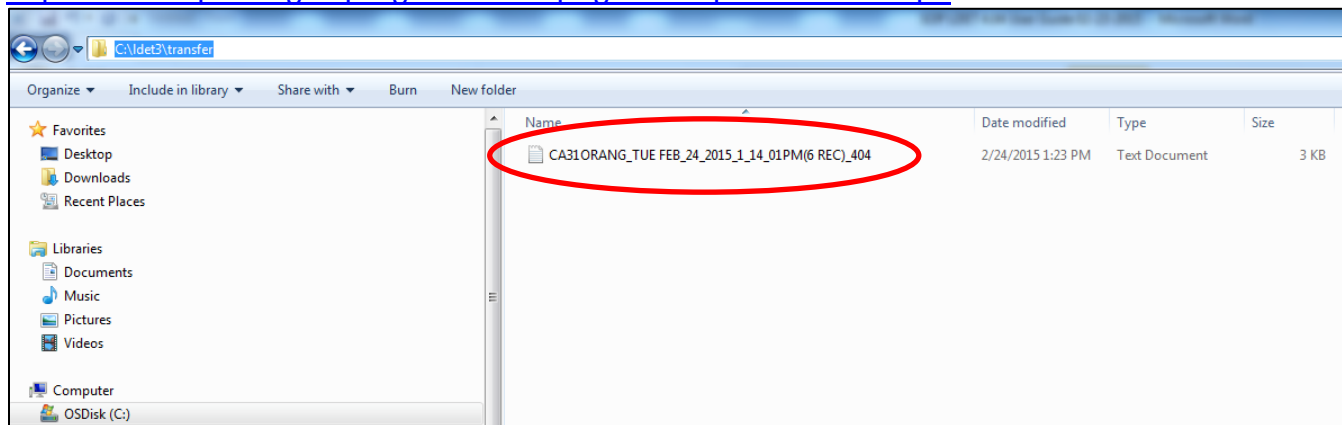
Example Location of the File Containing the Exported Laboratory Results for Transfer to OA

12 Exporting All Laboratory Results for Local Use

You can also export all your LDET data to an Excel file for your use locally. To do this, click the "Comprehensive Export" button the LDET Main Page.

To Export all Laboratory Records for Local Use, Click the "Comprehensive Report" Button

LDET Standard Operating Procedures

This opens the LDET Comprehensive Report screen, which shows all the laboratory result records in LDET. Click the "Export All Data" button to export all your laboratory results. Note that this process creates a laboratory result-based file, meaning that only cases with laboratory records will be exported.

Click "Export All Data" in the LDET Comprehensive Report Screen

A box appears telling you where the file containing the exported laboratory results has been created by LDET. In the case below the file was created in "C:\ldet3\export". Write this location down before proceeding. Click "OK" to proceed.

Box Showing the Location where the Laboratory Results were Exported; Write it Down and Click "OK"

LDET Standard Operating Procedures

Then Click "Close Form" to return to the LDET Main Page.
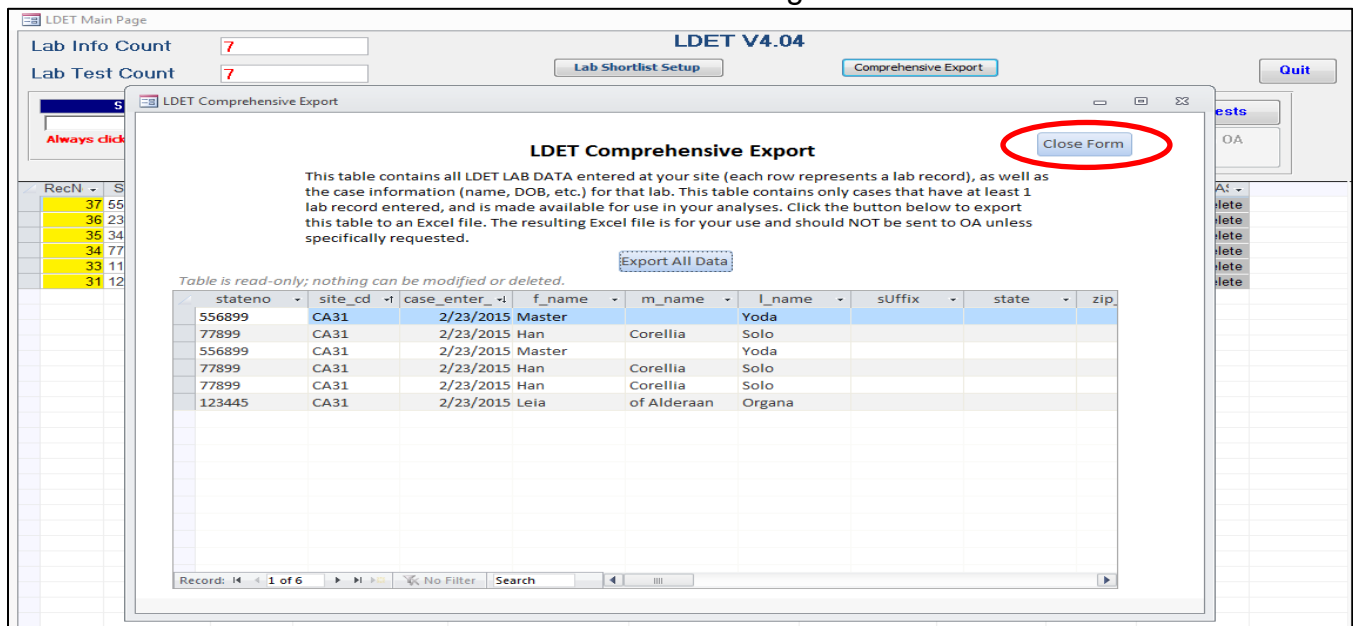
Click "Close Form" to Return to the LDET Main Page

The location of the example file containing all exported laboratory results for local use is shown below for this example. The location may be different on your system.
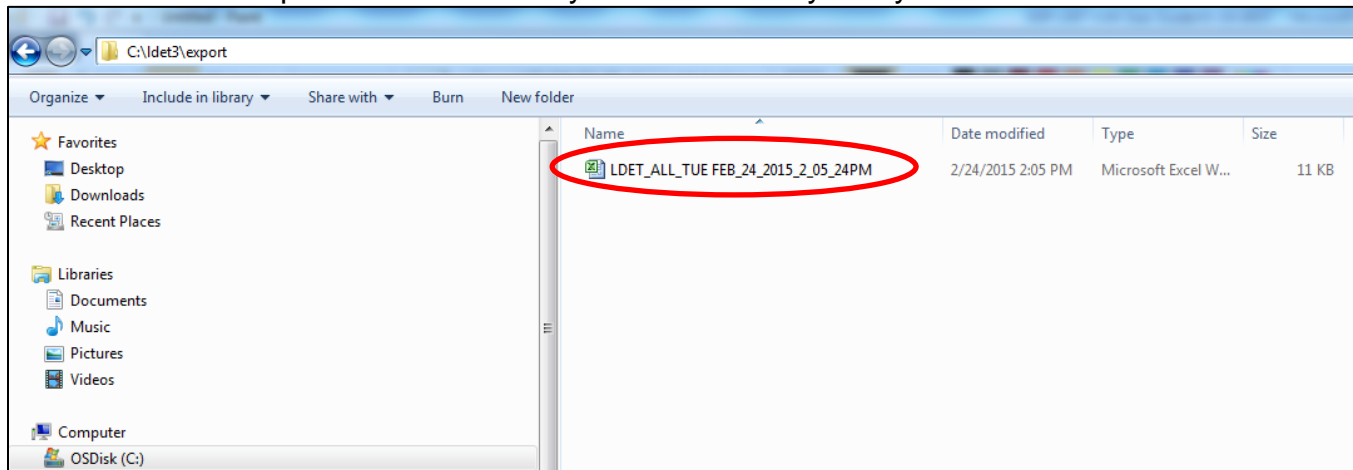

Example Location of the File Containing all Exported Laboratory Results for Local Use

Below is a snapshot of the contents of the example Excel file containing the exported labs for local use.

Contents of the File Containing the Exported Laboratory Results for Local Use

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13 Appendix A: Screen Location and Details of LDET Variables

Variable	Screen	Details
Accession No.	Add Lab Test	Required for first 90 days of HIV+ result. Optional 91+ days after first non-negative result.
CD4 Count	Add Lab Test	This is a required field and cannot be blank for CD4 results.
CD4 Percent	Add Lab Test	Optional, but please enter the correct information if available.
Date Entered	Add Lab Test	System generated, so field is locked.
Date Lab Case Entered	Lab Info	System generated, so field is locked.
Date of Birth	Lab Info	This is a required field and cannot be blank.
Date Received from Lab	Add Lab Test	Optional, but please enter the correct information if available.
Differentiating Result	Add Lab Test	This is a required field and cannot be blank for Type Differentiating results.
Document Type	Lab Info	Default entry is "004", the eHARS code for a laboratory document. Field is locked.
First Name	Lab Info	This is a required field and cannot be blank. Validation control forces user to enter value.
Lab CLIA No.	Add Lab Test	This is a required field and cannot be blank. CLIA number of performing laboratory.
Lab Interpretation	Add Lab Test	This is a required field and cannot be blank for Quantitative Viral Load results.
Lab Name	Add Lab Test	Optional. For use ONLY when laboratory CLIA is not available. Contact LDET technical support to add CLIA for future use.
Lab Result	Add Lab Test	This is a required field and cannot be blank. The units are automatically entered by LDET when required.
Lab Test Name	Add Lab Test	This is a required field and cannot be blank. Validation control forces user to select the value from a drop-down list.
Last Name	Lab Info	This is a required field and cannot be blank. Validation control forces user to enter value.
Manufacturer	Add Lab Test	Optional, but please enter the correct information if available. Manufacturer of the test upon which the result is based.
Medical Record No.	Lab Info	Optional, but please enter the correct information if available.
Middle Name	Lab Info	Optional, but please enter the correct information if available.

LDET Standard Operating Procedures

Variable	Screen	Details
Parent ID	Lab Info	No input required. OA will populate. Field is disabled.
Prison No.	Lab Info	Optional, but please enter the correct information if available.
Rapid Test?	Add Lab Test	Optional, but please enter the correct information if available.
Record Number (RecNo)	Lab Info	System generated, so field is locked.
Result Date	Add Lab Test	Optional, but please enter the correct information if available.
Rollup Number	Lab Info	No input required. OA will populate. Field is disabled.
Sex at Birth	Lab Info	This is a required field and cannot be blank.
Site Code	Lab Info	This is a required field and is locked with the site code that initially selected.
Specimen Collection Date	Add Lab Test	This is a required field and cannot be blank. Validation control forces user to enter a valid value.
STATENO (State Number)	Lab Info	This is a required field and cannot be blank. Validation control forces user to enter and then validate value.
Suffix	Lab Info	Optional, but please enter the correct information if available. Suffix of the case name. (i.e., SR, JR, II or III)

14 Appendix B: Laboratory Test Names, Results, and Units in LDET/eHARS

Laboratory Test Name	Result	Units
HIV Antibody Tests (Non-Type Differentiating)	POS, NEG, IND	NA
HIV-1 EIA		
HIV-1/2 EIA		
HIV-2 EIA		
NON-TYPE DIFF. HIV 1/2 AG/AB		
HIV-1 WESTERN BLOT		
HIV-2 WESTERN BLOT		
HIV-1 IFA		
HIV Antibody Tests (Type Differentiating)	HIV-1, HIV-2, BOTH, IND, NTHR	NA
HIV-1/2 TYPE DIFFERENTIATING		
HIV Detection Tests (Qualitative)	POS, NEG, IND	NA
HIV-1 P24 ANTIGEN		
HIV-1 RNA/DNA NAAT (QUAL)		
HIV-1 CULTURE		
HIV-2 RNA/DNA NAAT (QUAL)		
HIV-2 CULTURE		
HIV Detection Tests (Quantitative)	< Below Limit, = Within Limit, > Above Limit & (Number)	C/ML
HIV-1 RNA/DNA NAAT (QUAN)		
HIV-2 RNA/DNA NAAT (QUAN)		
Immunologic Tests	(Number)	
CD4 COUNT		CNT
CD4 PERCENT		PCT
Retired Tests	POS, NEG, IND	NA
HIV-1 RNA PCR (QUAL)		
HIV-1 PROVIRAL DNA (QUAL)		
RAPID		
HIV-1 RNA NASBA	< Below Limit, = Within Limit, > Above Limit & (Number)	C/ML
HIV-1 RNA BDNA		
HIV-1 RNA RT-PCR		
HIV-1 RNA OTHER		

Note: Some tests have been "retired" that were available in earlier versions of LDET. Although these retired tests are still frequently being used, they should now be entered as the general type of test. For example, "HIV-1 RNA BDNA" and "HIV-1 RNA RT-PCR" are no longer listed in the drop-down list, because these quantitative viral load tests should now be entered as "HIV-1 RNA/DNA NAAT (QUAN)." Similarly, the retired "HIV-1 RNA PCR (QUAL)" and "HIV-1 PROVIRAL DNA (QUAL)" should now be entered as "HIV-1 RNA/DNA NAAT (QUAL)." Whether a test was rapid or not can now optionally be reported for all applicable tests.